

REMARKS

Claims 1-8 are pending in this application. Applicant has amended claim 1. The amendments do not introduce new matter within the meaning of 35 U.S.C. §132. Basis for the claim amendments is found on page 2, lines 18-19; page 4, lines 16-20; page 15, lines 4-8; in claims 1-8 as originally filed; and elsewhere throughout the specification and claims. Accordingly, entry of the amendments is respectfully requested.

**1. Rejection of Claims 1-8 under 35 U.S.C. §112,
first paragraph**

The Office Action rejects claims 1-8 under 35 U.S.C. §112, first paragraph, for the following reasons:

"[T]he specification, while being enabling for a method of treating cell lines established from samples of cystic fibrosis patient resulting from an abnormal expression of genes caused by aberrant splicing in cells, comprising administering to the cells, an naturally occurring alternative splicing factor (ASF) by transfected the cells with expression vector to produce the ASF, whereby the abnormal expression shifts towards normal expression of the gene, does not reasonably provide enablement for a method of treating individual suffering from a disease resulting from an abnormal expression of genes caused by aberrant splicing in cells, wherein the disease and the abnormal genes are not defined, comprising administering to the cells or to tissue or organs of the individual comprising the cells, an ASF, whereby the abnormal expression shifts towards normal expression of the gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims."

Applicant previously traversed this rejection in the Response and Amendment filed September 22, 2003. Based on the literature references submitted, it is apparent that Applicant's experimental and prophetic examples have been borne out, and that the ordinarily skilled artisan has been able to use the methods disclosed by Applicant for using an ASF in the *in vivo* treatment of aberrant splicing disorders.

To advance prosecution, Applicant has amended claim 1 commensurate in scope with the specific, exemplary aberrant splicing mechanisms of exon inclusion and/or exon skipping, as disclosed at page 2, lines 18-19, page 4, lines 16-20, page 15, lines 4-8, and elsewhere in the Specification. This amendment is made without prejudice or disclaimer of the remaining subject matter of claim 1 as filed. Applicant reserves the right to pursue the remaining subject matter disclosed and originally claimed in this application in a continuing application.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 1-8.

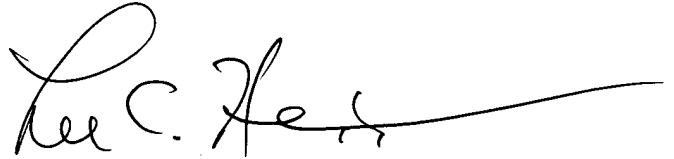
CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be novel and fully enabled. The Examiner is therefore respectfully requested to reconsider and withdraw the rejections of remaining claims 1-8 and allow all pending claims presented herein for reconsideration. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,

NATH & ASSOCIATES PLLC



Date: December 5, 2003

By:

Gary M. Nath
Registration No. 26,965
Todd L. Juneau
Reg. No. 40,669
Lee C. Heiman
Reg. No. 41,827
Customer No. 20529

NATH & ASSOCIATES PLLC

1030 15th Street, N.W., 6th Floor
Washington, D.C. 20005
Tel: (202)-775-8383
Fax: (202)-775-8396
GMN:TLJ:LCH Supp ROA2.wpd